Message

**From**: Michael Honeycutt [Michael.Honeycutt@tceq.texas.gov]
**Sent**: 8/6/2019 1:15:17 PM
**To**: Casso, Ruben [Casso.Ruben@epa.gov]
**Subject**: FW: Media inquiry: Bloomberg wants response to Elena Craft

Interesting article. Here's a response we sent to the reporter.

Mike

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**From:** Sabine Lange
**Sent:** Tuesday, July 30, 2019 2:39 PM
**To:** Brian McGovern <Brian.McGovern@Tceq.Texas.Gov>; Ryan Vise <Ryan.Vise@Tceq.Texas.Gov>
**Cc:** Michael Honeycutt <Michael.Honeycutt@tceq.texas.gov>; Joseph Haney <Joseph.Haney@tceq.texas.gov>
**Subject:** RE: Media inquiry: Bloomberg wants response to Elena Craft

Ryan and Brian,

We have included an additional paragraph at the beginning of our response that more simply and succinctly summarizes our message. However, we think that it is also important to include the more technical response as well, because Elena's comments to the reporter were very technical and were fundamentally incorrect.

Dr. Craft seems to be confusing the TCEQ's ethylene oxide (EO) dose-response assessment with one of the peer-reviewed papers that was referenced in our document (Kirman and Hayes, 2017). In contrast to Dr. Craft's characterization, the TCEQ conducted a non-threshold assessment that uses the same data that EPA used from a United States-based group of workers to calculate air concentrations of EO that are expected to cause minimal cancer risk for the general public. The information from the Kirman and Hayes (2017) study was not used to calculate the final EO cancer risks, but rather was used to put risk results into context. We confirmed the validity of the standard mathematical method we utilized by demonstrating that our selected model assessment could accurately reproduce the cancer mortality data in the group of US workers (EPA's model did a poor job of predicting the cancer risks in the group of US workers). This validation demonstrates that TCEQ chose an appropriate model for determining the cancer risks of exposure to EO. We appreciate Dr. Craft taking the time to provide comments on our assessment, and we welcome any and all further comments. More detailed responses to Dr. Craft's comments are included below.

Dr. Craft is incorrect in many of the statements she makes about our assessment, including:

1. That we derived threshold values for EO;
2. That we used the Kirman and Hayes (2017) analysis as the basis for our risk-based value for EO;
3. That we conducted a meta-analysis;
4. That we used data-sets from around the world;

5. That we used EO-hemoglobin adducts as a biomarker of exposure for dose-response modeling; and
6. That we forced the data to fit the model.

Dr. Craft focuses on the Kirman and Hayes (2017) work at the beginning of her comments, so perhaps she was confusing their work (the purpose of which was to determine endogenous EO levels in the body), with our carcinogenic dose-response assessment of EO.

The following is our clarification of Dr. Craft's misrepresentations:

1. The TCEQ is not conducting a threshold assessment or deriving threshold values, but rather is assuming cancer risk all the way down to zero dose with no threshold.
2. The work of Kirman and Hayes (2017) was used as supporting information, along with dozens of other studies and other lines of evidence (e.g. background EO concentrations, mutagenicity, epidemiological analysis, animal studies, etc). In particular Kirman and Hayes provided information about how much EO the body normally produces. This supporting information was not the basis of our derived EO risk value, but rather was used to provide context for our and EPA's EO values.
3. We did not conduct a meta-analysis. The TCEQ uses the same NIOSH worker cohort study data as was used by the EPA to derive non-threshold risk-based values for lymphoid cancer caused by EO.
4. The datasets that the TCEQ assessed for deriving risk-based values for EO were 2 United States-based worker cohort studies: the NIOSH cohort (which both the TCEQ and the EPA ultimately used to derive EO values) and the Union Carbide cohort (UCC).
5. The TCEQ did not use EO-hemoglobin adducts as a biomarker of EO exposure for our dose-response modeling. We used the exposures estimated by the NIOSH and UCC study authors, which was based on measured and modeled EO air concentrations.
6. Not only did the TCEQ not force the cohort data to fit our dose-response model, we actually demonstrate mathematically that our model fits the data well, and our model fits the data much better than EPA's model does. See Figures 8 through 12 on pages 42-46 of the Development Support Document. Because our model fits the data well, and better than EPA's model, our model can better estimate ethylene oxide risk to the public.

Our document demonstrates that our assessment is more accurate than EPA's and is supported by multiple and convincing lines of scientific evidence (e.g., considerations of biological plausibility, reality checks on background incidence, model fit to the data, etc.).

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**From:** Brian McGovern
**Sent:** Tuesday, July 30, 2019 8:28 AM
**To:** Michael Honeycutt <Michael.Honeycutt@tceq.texas.gov>; Susan Johnson <susan.johnson@tceq.texas.gov>
**Cc:** Ramiro Garcia <ramiro.garcia@tceq.texas.gov>; Tonya Baer <Tonya.Baer@tceq.texas.gov>; Cynthia Gandee <Cynthia.Gandee@tceq.texas.gov>; Jayme Sadlier <jayme.sadlier@tceq.texas.gov>; Tracy Miller <tracy.miller@tceq.texas.gov>; Sabine Lange <Sabine.Lange@tceq.texas.gov>; Donna Huff <donna.huff@tceq.texas.gov>; Kim Herndon <Kim.Herndon@tceq.texas.gov>; Mike Wilson <mike.wilson@tceq.texas.gov>; Steven Hagood <steven.hagood@tceq.texas.gov>; Chris Owen <chris.owen@tceq.texas.gov>; Jonathan Walling <jonathan.walling@tceq.texas.gov>; Anita Keese <anita.keese@tceq.texas.gov>; David Ramirez <david.ramirez@tceq.texas.gov>
**Subject:** Media inquiry: Bloomberg wants response to Elena Craft

Dr. Honeycutt and team,

We have another inquiry from Bloomberg. The reporter has received quotes from Elena Craft concerning TCEQ's data on ethylene oxide, and wants to give the agency the opportunity to respond.

He would like a response by COB today, if possible.

I have input/comment from Toxicologist Elena Craft, an Austin-based toxicologist who is Environmental Defense Fund's senior director for climate and health. Below is the comment I have from her, communicated last week. I wish to extend the opportunity to the agency to offer comment/response to her comment she offered as it relates to proposed efforts to revise a cancer risk assessment for ethylene oxide, public comment period ending Sept. 26.

Comments by the EDF toxicologist Elena Craft:

"We will have more on this soon, but just taking an initial look at some of material that TCEQ is using to assess threshold values of EtO, there are real problems with the data that they are relying on for their assessment, specifically the work from Kirman and Hays.

"To summarize, TCEQ has done a meta-analysis using disparate data sets from disparate countries around the world to account for EtO exposure. What you have is a very mixed bag of people, many of whom have not been properly controlled for potential occupational exposures.

"TCEQ's criteria for inclusion in the meta-analysis are very loose and there is no sensitivity analysis to see what the impact might be of dropping some folks (i.e., Do your conclusions still hold if remove datasets that may not have been properly controlled?).

"It is also clear that there is a specific phenotype in some people that is more active/sensitive to hemoglobin adducts, which is the biomarker that they are using for exposure.

"If there is a difference across study populations in the percentage with this phenotype, it could make these studies non-comparable, which would make their meta-analysis irrelevant. It also seems that they are trying to force the data to fit into the model that they are using.

"Overall, we have very little confidence in the assessment of data put forward by TCEQ on a compound that is contributing to some of the largest cancer risks in people across the nation."

Thanks,

**Brian McGovern**
TCEQ Media Relations Specialist

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